DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6009

October 19, 1999

WARNING LETTER

CERTIFIED MAIL-
RETURN RECEIPT REQUESTED

Michael Turner
President
Somerset Medical Center
110 Rehill Avenue
Somerville, New Jersey 08876

File No.: 00-NWJ-07

Dear Mr. Turner:

During an inspection of your blood bank, located at 100 Rehill Avenue, Somerville, New Jersey on September 13-22, 1999, an Investigator from this office documented violations of Section 501 (a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Parts 600-680, as they relate to the collection, processing and testing of blood and blood components. These deviations were cited on an FDA483 List of Inspectional Observations issued on September 22, 1999.

The significant observations are as follows:

1. Failure to identify, quarantine and destroy an unsuitable unit of blood, in accordance with written procedures. For example, Unit [redacted], tested reactive for Hepatitis B Core. This unit was processed, released and transfused.

2. Failure to maintain complete and accurate records from which unsuitable donors may be identified in order to defer donors from making subsequent donations. For example, the donor of Unit [redacted], reactive for Hepatitis B Core, was not temporarily deferred and donated Unit [redacted] approximately six months later, which also tested reactive. This error was discovered during the inspection and the unit was destroyed.

3. Failure to follow "Reactive Unit Audit" procedure, resulting in the aforementioned reactive unit, not being audited for unit disposition and donor status.

4. Written procedures are not adequate for the investigation of error and accidents, in that they do not include procedures for identifying and correcting factors contributing to problems. There is no documentation to evidence that all Blood Bank Problem Reports were investigated, or that corrective and preventative action was taken.

5. There is no documentation to assure that all personnel have a thorough understanding of the procedures or control operations they perform, the necessary training and adequate information concerning the application of pertinent provisions of the CFR to their respective functions. For example, volunteers responsible for conducting donor interviews and determining donor suitability are not trained annually as required for employees.

6. Donor records are inadequate, in that donor suitability cannot be determined from the information documented. For example, malarial risk is not adequately documented on the donor questionnaire, in regard to areas visited or dates of travel.

The above deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of federal regulations, with regard to blood collection, processing, testing and distribution. You should take prompt action to correct these deviations. Failure to implement corrections may result in regulatory action without further notice.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including supporting documentation and an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrective measure will be implemented. Your written response should be sent to the Food & Drug Administration, New Jersey District Office, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes B. Mota, Compliance Officer.

Sincerely,

for Douglas I. Ellsworth
District Director
New Jersey District